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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,972	07/17/2003	Ross S. Tsugita	1001.1421103	2230

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EXAMINER	
BLATT, ERIC D	

ART UNIT	PAPER NUMBER
3734	

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10/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/621,972	TSUGITA, ROSS S.	
	Examiner	Art Unit	
	Eric Blatt	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-81* is/are pending in the application.

4a) Of the above claim(s) *72-77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-71 and 78-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 63 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 63 recites that the first catheter includes an infusion port within the proximal end region. The original disclosure discussed only an infusion port on the first catheter located at the distal end region of the first catheter. (See Figure 5)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 78 recites the limitation "the outer catheter shaft." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 53-58, 60-65, and 68-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (WO 99/22673) in view of Patel (4,832,028).

Gray discloses guidewire 30, filter 50 and stent (page 6, lines 15-17). Gray fails to disclose a first shaft (claim 53) or outer catheter shaft (claim 68) with a balloon coupled thereto. However, Patel teaches that a guiding catheter 11 with a balloon 25 should be used with a dilating catheter 29 in order to obtain the advantage of guiding the dilating catheter 29 within the vasculature while the balloon 25 holds the guiding catheter in place (col. 1, lines 43-52 and col. 3, lines 15-27). It would have been obvious to use a guiding catheter with a balloon with the Gray dilating catheter so that it too would have this advantage. The guiding catheter is the claimed “first shaft” (claim 53) or “outer catheter shaft” (claim 68). The guiding catheter taught by Patel has an end region extending from port 27 to the distal tip of the catheter. The portion of this end region that lies proximal to the balloon 25 is considered a proximal end region, and the portion of this end region that lies distal to the balloon 25 is considered a distal end region. There is a perfusion lumen running through this end region that allows a perfusing fluid (oxygenated blood) to pass into infusion port 27, through the perfusion lumen, and out of the distal end of the catheter and toward an inner surface of the body lumen to flush embolic debris into the filter. Since the perfusion lumen will be positioned

within a body lumen, literally any direction will be toward an inner surface of the body lumen.

Regarding claim 68, there is a lumen of the guiding catheter taught by Patel running from the proximal end of the catheter shaft to the distal end of the catheter shaft. Said lumen is capable of allowing fluid to flow from the proximal end to the distal end to flush embolic debris into the filter. Although there is a port 27 through which some quantity of the fluid might escape, at least some fluid will exit through the port at the distal end of the catheter shaft.

As to claims 56 and 69, Gray fails to disclose that the stent is self expanding and is retained in a collapsed configuration by a retaining sleeve. However, it is old and well known in this art to make stents self-expanding in order to obtain the advantage of enabling them to automatically expand when released by the retaining sleeve. It would have been obvious to make the Gray stent self expanding so that it too would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03). Alternatively, it would have been obvious to use the first catheter as a retaining sheath for the stent since deployment systems wherein a stent is held between an inner and an outer catheter were also notoriously old and well known in the art.

Applicant has previously argued that the guiding catheter 11 and balloon 25 of Patel are not configured to stop fluid from outside the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded because the guide catheter 11 comprises port 27 which allows some quantity

of blood to flow into the lumen of guide catheter 11 and to perfuse out of the tip 21. In response, Examiner first notes that the language requires only that the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft from flowing distally past the distal region of the shaft. Blood that flows into port 27 is not outside of the first catheter shaft. Moreover, looking to Applicant's current claims 63 and 64, Applicant has claimed precisely such an infusion port in combination with the limitation that the balloon and catheter are capable of preventing flow past the balloon. From this, it appears that Applicant does not consider the existence of an infusion port proximal to the balloon to exclude the prevention of fluid flow as claimed.

Claims 59, 66, 67 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (WO 99/22673) in view of Patel (4,832,028) as applied to claims 53 and 56 above, and further in view of Dubrul (US 6,258,115).

Regarding claim 59, Dubrul teaches that it was known for self expanding stents to be thermally activated. (Column 9, Lines 59-60) It would have been obvious to one of ordinary skill in the art to use a thermally activated self-expanding stent since such stents were well known alternatives to the balloon expandable stents discussed in Gray and this substitution would not have produced unexpected results.

Regarding claims 66, 67 and 78-81, Dubrul teaches providing a stenting and distal protection system with an aspiration device so that dislodged emboli can be aspirated from the vessel prior to un-deploying the filter and removing it. It would have been obvious to one of ordinary skill in the art to modify the system taught by Gray in

view of Patel by providing an aspiration catheter in order to remove debris from the vessel and filter while the filter is disposed in the lumen as taught by Dubrul. Further, it would have been obvious to size the aspiration catheter such that it is capable of being slidably disposed in either the first/outer catheter shaft or the second/inner catheter shaft in order to allow the aspiration catheter to easily reach the procedure site.

Double Patenting

Claims 53-71 and 78-81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,168,579. Although the conflicting claims are not identical, they are not patentably distinct from each other because the small differences in the wording between the sets of claims do not define significant, non-obvious distinctions.

Response to Arguments

Applicant's arguments filed 6-11-2009 have been fully considered but they are not persuasive.

Applicant argues that the balloon taught by Patel is incapable of stopping fluid from outside the guiding catheter proximal to the balloon from flowing distally past the balloon when the balloon is expanded since Patel teaches providing a port 27 which allows blood to flow through the interior of the distal end of the catheter. In response, Examiner first notes that the language requires only that the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft from flowing

distally past the distal region of the shaft. Blood that flows into port 27 is not outside of the first catheter shaft. Moreover, looking to Applicant's own disclosure (See at least Figure 5 and claims 63 and 64), Applicant has disclosed precisely such an infusion port proximal to the balloon and stated that the balloon of this device is capable of preventing flow past the balloon. From this, it appears that Applicant does not consider the existence of an infusion port proximal to the balloon to exclude the prevention of fluid flow as claimed.

Applicant additionally argues that the guiding catheter taught by Patel does not have a lumen capable of allowing fluid to flow from a proximal end region (claim 53) or proximal end (claim 68) of the catheter to a distal end region (claim 53) or a distal end (claim 68) of the catheter, submitting that the presence of port 27 would prevent such a function. In response, Examiner first notes that the language of claim 53 allows the end region of the guiding catheter proximal to the balloon to be taken as a proximal end region and the end region of the guiding catheter distal to the balloon to be taken as a distal end region. Under this interpretation, the claimed perfusion lumen lies entirely distal to port 27 of the Patel device, and the argument is rendered moot. Regarding the language of claim 68, the Patel guiding catheter has a lumen running from its proximal end to its distal end. This lumen is capable of allowing fluid to pass from the proximal end to the distal end of the catheter. Although some of the fluid may escape from port 27, at least some of the fluid will reach the port at the distal end of the guiding catheter. Furthermore, in claims 63 and 64, Applicant claims that a perfusion port very much like port 27 of Patel is provided proximal to the balloon, and places this recitation in

combination with the recitation that the catheter defines a perfusion lumen configured for the passage of perfusing fluid supplied at the proximal end region therethrough so as to flush embolic debris into the filter. This disclosure is taken as an admission that provision of a perfusion port on a catheter does not render a catheter lumen incapable of allowing fluid to pass from the proximal end of the catheter to the distal end of the catheter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. B./
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734